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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,570	09/15/2003	Jonathan S. Stinson	06530.0374-00000	9734

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
06/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,570	STINSON ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-50* is/are pending in the application.

4a) Of the above claim(s) *35-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-34 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *091503*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

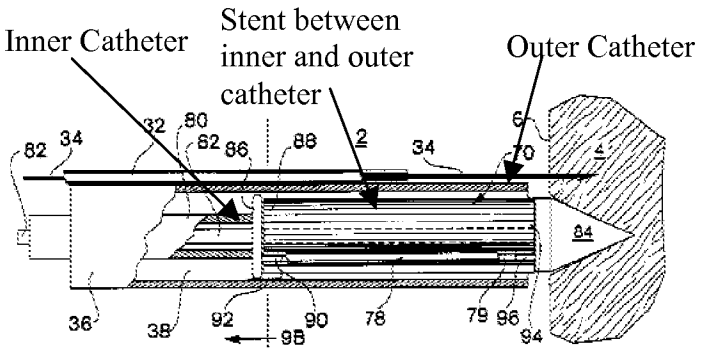
Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 24, 26-28, 30, 31 and 33 rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al (USPN 6,458,092).

3. Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter (see below). The stent can be a braided filament (Fig. 5a, b) or non-absorbable plastic (Col 12, line 64). The stent has uniform diameter (Fig. 1B) and is shaped to include a waist of lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 1D). The perforating means is a retractable needle.



Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 24, 25, 29-31, 33, 47, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps et al (USPN 6,290,728) in view of Ravenscroft (US 5,702,418).**

6. Phelps discloses a stent delivery system comprising: an inner catheter (22) with a first lumen; perforating means (16) slidably disposed in the first lumen; an outer catheter (26) adapted or capable of axial movement relative to the inner catheter (C 6: L23 states that the outer sheath is withdrawn); a self expandable stent (20) disposed between the inner and outer catheter. The stent is coaxially mounted over the inner catheter. The stent is made of bio-absorbable material (Col 7, line 33). One embodiment of a stent has uniform diameter (Fig. 12) and another is shaped to include a waist of

lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 4). The perforating means is a retractable needle. The stent is adapted to or capable of draining a gastric pseudoscyst and the stent will have a diameter larger than a diameter of an endobiliary tube (C 9:L21 Phelps contemplates using the stents as billiary stents).

7. Phelps does not disclose that the system further comprises an endoscope for receiving the outer catheter.

8. However, Ravenscroft discloses a stent delivery device incorporating an endoscope (71) with an inner catheter (17), outer catheter (24) and self expanding stent (20). The endoscope receives the outer catheter and is configured for (capable of) intraoral introduction. Ravenscroft discloses that the endoscope with viewing channel allows the surgeon to determine whether the stent will be properly placed or whether it may need to be relocated (C7: L42-67).

9. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of an endoscope into the delivery device of Phelps in order to achieve better placement of the stent during delivery.

10. Regarding claim 50, Phelps is silent as to the outer catheter extending over a majority of length of the inner catheter. However Ravenscroft discloses a similar delivery device where the outer catheter does extend over the majority of the length of the inner catheter. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sheath or outer catheter that extends over the length of the inner catheter since it is a technique that is well known in the art. It is

common for the sheath to extend the length of the catheter and out of the body so that the user will be able to grasp it and withdraw to deploy the stent.

11. Claims 24, 25- 28, 30, 33, 34, 47, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (USPN 6,599,315) in view of Haarstad et al (USPN 6,533,753) further in view of Ravenscroft (USPN 5,702,418).

12. Wilson discloses a stent delivery system comprising: an inner catheter (120) with a first lumen (125) with a guide wire (150) slidable disposed in the first lumen; a second lumen (126) with a guidewire (151) slidably disposed in the second lumen; and a self expandable stent (20) (Col 6, line 62) coaxially disposed over the inner catheter and an outer catheter (guiding catheter (C8: L58) that is adapted to move axially relative to the inner catheter. The stent is made of non-absorbable plastic material (Col 6, lines 38-42). The stent has uniform diameter. The stent is adapted to or capable of draining a gastric pseudocyst. The stent will have a diameter larger than a diameter of an endobiliary tube when the endobiliary tube is in an infant.

13. Wilson does not disclose that the first guidewire is a perforating means that is a retractable needle.

14. Haarstad discloses that it is well known in the art to use a stiff guidewire to penetrate lesions referred to as “chronic total occlusions” (Col 1, lines 40-51). In this case the guidewire is considered the perforating means or needle.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a stiff guidewire into the stent delivery device in

order to more easily traverse a stenosis that may be fully occluding the vessel. It is well known in the art as evidenced by Haarstad.

16. Wilson modified by Haarstad does not disclose that the system further comprises an endoscope for receiving the outer catheter.

17. However, Ravenscroft discloses a stent delivery device incorporating an endoscope (71) with an inner catheter (17), outer catheter (24) and self expanding stent (20). The endoscope receives the outer catheter and is configured for (capable of) intraoral introduction. Ravenscroft discloses that the endoscope with viewing channel allows the surgeon to determine whether the stent will be properly placed or whether it may need to be relocated (C7: L42-67).

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of an endoscope into the delivery device of Wilson modified by Haarstad in order to achieve better placement of the stent during delivery.

19. Regarding claim 26, Wilson modified by Haarstad does not disclose that the stent is made of braided filamentary material, but does disclose that the stent can be virtually any pattern. However Ravenscroft discloses that it is old and well known for stents to be made from braided wire. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a stent of braided filamentary wire for the undulating stent of Wilson since the two stents were art recognized equivalents at the time of the invention was made. One of ordinary skill in the art would have found it obvious to substitute the braided filamentary stent for the undulating stent, since substitution of one known element for another would have yielded predictable results.

20. Regarding claim 50, Wilson modified by Haarstad is silent as to the outer catheter extending over a majority of length of the inner catheter. However Ravenscroft discloses a similar delivery device where the outer catheter does extend over the majority of the length of the inner catheter (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sheath or outer catheter that extends over the length of the inner catheter since it is a technique that is well known in the art. It is common for the sheath to extend the length of the catheter and out of the body so that the user will be able to grasp it for withdrawing and deploying the stent.

21. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (USPN 6,599,315) in view of Haarstad et al (USPN 6,533,753) in view of Ravenscroft as applied to claim 47/1 above and further in view of Patterson (USPN 6,165,209).

22. Wilson in view of Haarstad discloses the invention substantially as claimed as stated above except for the dimensions of the diameter of the stent. Wilson discloses that the stent is used for repairing an artery having septal perforations.

23. Patterson discloses that it is typical for stents that are used in arteries to have a diameter from 4 to 10 mm (C6: L 50-55).

24. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a diameter of about 8mm into the stent disclosed by Wilson since it is well known in the art to modify the size of the stent depending on the location

of the body in which it is placed. Patterson discloses that it is well known to use a stent with the claimed diameter. It is further obvious to one of skill in the art to change the size of stents based on the size of the patient. Such a modification would have involved a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

25. **Claims 32 and 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps in view of Ravenscroft and in view of Anderson (USPN 6,290,728).**

26. Phelps modified by Ravenscroft discloses the invention substantially as claimed except for the exact dimensions. Phelps modified by Ravenscroft also discloses that in addition to being used in the myocardium, the stent system can be used for billiary or esophageal stents (C 9:L21).

27. Anderson discloses a billiary stent and stents used for shunts that fall within the claimed parameters (C7:L16-30).

28. It would have been obvious to one having ordinary skill in the art at the time of the invention to change the size of the stent since the claimed dimensions are well known in the art for use in billiary stents. It is further obvious to one of skill in the art to change the size of stents based on the size of the patient. Such a modification would have involved a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

Applicant's arguments with respect to claims 24-34 and 47-49 have been considered but are moot in view of the new ground(s) of rejection. All of the issues provided by the applicant have been addressed above in light of the newly combined references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731